Remarks

The Office Action mailed October 23, 2001 has been received and reviewed. Claims 1 through 19 are pending in the application. Claims 4 through 10, 12, 14 through 15, and 18 through 19 have been withdrawn from consideration. Claims 1 through 3, 11, 13, 16, and 17 stand rejected. The application is to be amended as previously set forth. All amendments are made without prejudice or disclaimer. Reconsideration is respectfully requested.

1. **Priority**

Applicants claim priority from an International Patent Application PCT/EP98/08169 filed 16 December 1998, which claims priority from European Patent Application EP 97203974.7 filed 17 December 1997. A certified copy of European Patent Application EP 97203974.7 is enclosed.

2. **Specification**

Guidelines were presented to the applicants for the preferred layout and content for patent applications and were suggested for the applicants use. The applicants have amended the application to comply with the guidelines.

The specification was objected to because of the following informalities: the genus and species of each organism was not italicized (*e.g.*, page 4, line 22 "Eisenia foetida" was not italicized), the presence of British spellings (*e.g.*, page 17, line 13 "utilises" should be changed to "utilizes"), and the presence of nucleotide and protein sequences that were not identified (*e.g.*, page 18 and page 20). The applicants have amended the specification as to correct the informalities. Withdrawal of the objections is thus requested.

3. **Claim Rejections under 35 U.S.C. § 112, first paragraph**

Claims 1-3, 11, 13 and 16-17, were rejected under 35 U.S.C. § 112, first paragraph, because the specification, while admittedly being enabled for SEQ ID NO: 1, assertedly failed to provide guidance as to "whether the peptides comprising SEQ ID NO: 3 or fragments or epitopes thereof

have cytolytic or trypanolytic activity." (Office Action, pages 4 and 5). Applicants respectfully traverse the rejection for the following reasons.

First, the specification is admitted by the Office as being enabling for the peptides of SEQ ID NO: 1 to have trypanolytic activity (Office Action, page 4, lines 9-10). Second, SEQ ID NO: 1 is a fragment of SEQ ID NO: 3. (*See,* Sequence Listing). Lastly, SEQ ID NO: 3 is the deduced amino acid sequence of CCF-1 cDNA, (*See,* Application (as filed), page 19, last paragraph; *see also,* Sequence Listing SEQ ID NOs: 2 and 3) and as described in Examples 6 and 7 of the specification, CCF-1 clearly has biological and *in vivo* activity. (Application (as filed), pages 21-24). Therefore, a person skilled in the art would be able to make and use the peptides as claimed in the present application without undue burden. Reconsideration and withdrawal of the rejections are thus requested.

4. **Claim Rejections under 35 U.S.C. § 112, second paragraph**

Claims 2, 11, 13 and 16-17 were rejected under 35 U.S.C. § 112, second paragraph, for assertedly failing to particularly point out and distinctly claim what the applicants regard as their invention. Specifically, it was thought that claims reciting "a functional fragment thereof" were unclear because "functional fragment thereof" could not be ascertained. (Office Action, page 5). Applicants respectfully traverse the rejection.

"Fragment" is defined in the specification in the last paragraph of page 9. (Application (as filed), page 9, lines 23-28). The specification also indicates that the fragments have "the essential cytolytic, trypanolytic and glucan-binding characteristics comparable to the whole protein." (Application (as filed), page 10, lines 4-6). Because these passages specifically define a "functional fragment", applicants respectfully request reconsideration and withdrawal of the rejections.

Claims 11, 16, and 17 were rejected under 35 U.S.C. § 112, second paragraph, for assertedly being indefinite for being "drawn to a pharmaceutical composition which only contains a peptide" and because no pharmaceutical carrier is contained in the composition. (Office Action, pages 5 and 6) (Emphasis in original). However, presently pending claims 11, 16, and 17 recite that the composition **comprises** at least a peptide. (Emphasis added). The term comprising "is synonymous

with 'including,' 'containing,' or 'characterized by,' is inclusive or open-ended and does not exclude additional, unrecited elements or method steps." M.P.E.P. § 2111.03. Therefore, claims 11, 16, and 17 are not limited as suggested by the Office. One of ordinary skill in the art would know which of the various pharmaceutical carriers is suitable for delivering the peptide. In view thereof, applicants respectfully request reconsideration and withdrawal of the rejection.

Claims 11, 16, and 17 were also rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite because the term "epitope" could not be ascertained. (Office Action, page 6). However, epitope is a term well-known to a person skilled in the art. Reconsideration and withdrawal of the rejections are respectfully requested.

5. **Claim rejections under 35 U.S.C. §102**

Claims 1 and 2 were rejected under 35 U.S.C. § 102(a) as being anticipated by Beschin et al. Applicants respectfully traverse the rejection. Applicants have submitted a certified copy of European Patent Application EP 97203974.7 filed on December 17, 1997 which predates the Beschin et al. reference published on September 18, 1998. Accordingly, applicants respectfully submit that Beschin et al. be removed as a reference and that the rejections be withdrawn.

Claims 1 through 3 and 13 were rejected under 35 U.S.C. § 102(b) as being anticipated by Bilej et al. Applicants respectfully traverse the rejection. The Bilej et al. abstract should be considered as non-enabling because a person skilled in the art would not be able to predict the exact amino acid sequence claimed by the applicants based on the disclosure in the Bilej et al. abstract. Also, without the exact amino acid sequences, one skilled in the art would not be able to anticipate that the claimed sequences, such as SEQ ID NO: 1, have trypanolytic activity. Therefore, reconsideration and withdrawal of the rejections are respectfully requested.

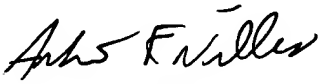
Claims 11 and 16 through 17 were rejected under 35 U.S.C. § 102(a) as being anticipated by Beschin et al. Applicants respectfully traverse the rejection. Since the priority document (European Patent Application EP 97203974.7 filed on December 17, 1997) predates the Beschin et al. reference published September 18, 1998, the Beschin et al. reference is no longer prior art. Applicants therefore request the rejections be withdrawn.

Claims 11 and 16 through 17 were rejected under 35 U.S.C. § 102(b) as being anticipated by Bilej et al. Applicants respectfully traverse the rejection. The Bilej et al. reference is non-enabling because a person skilled in the art would not be able to predict the exact amino acid sequence contained in the pharmaceutical composition as claimed by the applicants. Accordingly, reconsideration and withdrawal of the rejections are respectfully requested.

Conclusion

If any questions remain after consideration of the foregoing, the Office is kindly requested to contact applicants' attorney at the address or telephone number given herein.

Respectfully submitted,



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Date: January 23, 2002

Enclosures:
Appendix A
Appendix B
Copy of Notice to Comply
Paper copy of Sequence Listing
CRF copy of Sequence Listing
Statement under 37 C.F.R. §§ 1.821(g) and 1.825
Petition for extension of time (in duplicate)
Check No. in the amount of $200
Certified Copy of European Patent Application EP 97203974.7
Associate Power of Attorney